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STRATAGEM INTELLECTUAL PROPERTY MANAGEMENT LIMITED

To :	**EPO**
From :	**Dominic Schiller**
Date :	**30-Sep-2004**
Our Ref :	**P1603/WO**
Fax No :	**+49 89 2399 4465**
Total pages :	**22**

Response to Written Opinion Due 1 October 2004

Dear Sirs

Re: International Application No: PCT/EP 03/07859
Applicant: Caretek Medical Limited et al
International Patent Classification: A61M5/20
Our ref: P1603/WO

In response to the written opinion of 16.09.04 we offer the following comments and a revised claim set by way of reply. Our comments are numbered to correspond to the numbering used by the examiner:

Point III

1. Claim 57 is retained as practice in different jurisdiction varies.

Point IV

1. Claims 1-37 are directed to a drug delivery device which is adapted to deliver a packaged drug as claimed in claims 38-56. As such it is submitted that there is a common link although it is appreciated that again practice may vary in different jurisdictions.

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Point V

1-2. It is submitted that the revised claim 1 (and the revised claims 35 and 37) is/ are clearly distinguished from D1 and D2 by way of the introduction into the claims of the feature from page 12, 1st and 2nd paragraphs, (see also original claim 5 and page 4 2nd and 3rd paragraphs) namely that **said force generating means (14) and said force transmitting means (20) are configured to push the drug (16) from the packaging (18) into the human or animal body at a velocity of less than 20m/s.**

In this regard the examiner will readily appreciate that the force generating and force transmitting means of the cited devices differ from those of the claimed device in both type and configuration **due to the different functions they serve**. More precisely:

D1, US 2,398,544, discloses a **needle-free** device for injecting **liquids. Thus, the device has to generate a force which will allow the liquid to penetrate the skin.** Accordingly, the force generating means (24) and force transmitting means (20) are configured very differently to that of the device claimed.

Page 1, column 1, lines 6-17 sums it up in stating: "...wherein spring means is used to effect discharge of hypodermic liquid with **sufficient force** to cause self injection thereof, the pressure produced being such that there is initially **a sudden build up of the pressure to cause the liquid to puncture the skin...**"
Also, on page 1, column 2, lines, 31/2 it is made clear that the spring "**...is under considerable compression.**"
Indeed on page 2, column 1, lines 28-35 it is stated that the spring means **produces a liquid stream with a pressure of 1000lb/sq inch.**
Such an arrangement means the device is quite clearly **NOT** configured to push the drug out of the device **at a velocity of less than 20m/s as claimed.**

D2 – DE 3,839,287 (equivalent to US 5,026,343 to which reference is made below) also relates to a device for the **needle-free injection of liquids.** The therapeutic agent (4) is held within a membrane (3) in a cassette which is inserted into the device. The system is primed by using a **motor** (16) which draws back the casing (18) and the punch (15) until the top of the punch latches into position. The motor is then reversed to drive the casing back to the bottom end of the device. The system is actuated by releasing the catch (21) and the spring drives the plunger against the membrane and forces the therapeutic agent from the cassette.

It is clear from the description of the device, column 2 lines 26-28 which is referred to as a "pistol" that the liquid is "fired" through (and punctures) the skin and that accordingly a high pressure must be attained (hence the motor). Indeed, column 3 lines 38 to 41 states "the spring drives the punch forwardly in a **fast action**"

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Since D1 and D2 are silent on velocity we enclose a copy of an abstract from Pharmaceutical Research **19** (11): 1673-1679, November 2002
http://journals.kluweronline.com/article.asp?PIPS=454793
which clearly and unambiguously demonstrates that the devices of D1 and D2 do not comprise **force generating means (14) and force transmitting means (20) configured to push the drug (16) from the packaging (18) into the human or animal body at a velocity of less than 20m/s** BUT that in contrast will be configured to deliver a drug at a velocity in the order of **80-190m/s.**

Since the device of the claimed invention is used with a packaged drug (claims 38-56) which contain a skin piercing means (110;112) in the form of either a pioneer projectile or a needle the velocity needed to push the drug into the skin and hence the force generating and transmitting means and their configuration are consequently fundamentally different.

Point V
3-8. Due to differing requirements in different jurisdictions no specific action has been taken with respect to these points. All the same, based on the action taken in respect of the substantive issues raised in sub paragraphs 1 and 2 a favorable IPER is anticipated.

Yours faithfully

Stratagem IPM Ltd

Enc Revised Claim set
Copy of Pharmaceutical Research **19** (11): 1673-1679, November 2002

cc C Potter

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CLAIMS – showing amendments

1. A drug delivery device (10) comprising:

i) a housing (12);

ii) a means (14) for generating a force capable of pushing a drug (16) from a packaging (18) into a human or animal body;

iii) a means (20) for transmitting said force to push the drug (16) from the packaging (18) into the human or animal body; and

iv) a means (38, 42b) for triggering the device

wherein said force generating means (14) and said force transmitting means (20) are configured to push the drug (16) from the packaging (18) into the human or animal body at a velocity of less than 20m/s.

2. A drug delivery device as claimed in claim 1 wherein the housing defines:

i) an upper barrel (28), at one end of the device, which houses the force generating means (14); and

ii) a lower barrel (30), at the end remote from the upper barrel, which houses:

a) a packaged drug (100); and

b) the means (20) for transmitting said force to push the drug (16) from the packaging (18)

said lower barrel being in operative communication with said upper barrel and said packaged drug (100).

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3. A drug delivery device (10) as claimed in claim 2 further comprising

v) a means (22) for receiving the packaged drug (100); and

vi) a means (24) for priming the device.

4. A drug delivery device as claimed in any of the preceding claims wherein the means (14) for generating a force capable of pushing a drug (16) from a packaging (18) into a human or animal body delivers a force of from 10 - 40N.

5. A drug delivery device as claimed in any claim 2 wherein the means (20) for transmitting said force to push the drug (16) from the packaging (18) causes the drug to be pushed from the packaging at less than 10m/s.

6. A drug delivery device as claimed in claim 3 wherein said packaged drug (100) is slidably disposed in the means (22) for receiving the packaged drug.

7. A drug delivery device as claimed in any of claims 2 to 6 wherein the packaged drug (100) is slidably disposed in the lower barrel (30) and comprises a packaging (18) containing a drug (16), said packaging comprising a housing (18a, 18b) having a channel (106; 106a, 106b) running there through in which is disposed a drive pin or other element (108), a skin piercing means (110; 112) and the drug (16);
said housing further comprising

i) a region (102) allowing the packaged drug to be slidably mounted to the drug delivery device (10) at receiving means (22); and

ii) an end (104) adapted to engage and tension the skin.

8. A drug delivery device as claimed in claim 7 wherein the skin piercing means is a pioneer projectile (110), a syringe needle (112) or the head of a drug splinter.

9. A drug delivery device as claimed in claim 7 or 8 wherein the drive pin or other element (108) has a flat or enlarged head (108a).

10. A drug delivery device as claimed in claim 7, 8 or 9 further comprising a resilient means (114) below or otherwise in association with the drive pin or other element (108) to ensure the drive pin is withdrawn after use.

11. A drug delivery device as claimed in any of the preceding claims wherein the means (14) for generating the force capable of pushing the drug (16) is a spring.

12. A drug delivery device as claimed in claim 11 wherein the spring is a coil or gas spring.

13. A drug delivery device as claimed in claims 11 or 12 wherein the force generated by the spring is adjustable.

14. A drug delivery device as claimed in claim 13 wherein a screw cap (32) and compression bar (34) provide a means for adjusting the force generated by the spring.

15. A drug delivery device as claimed in any of claims 11 - 14 further comprising a spring follower (36).

16. A drug delivery device as claimed in any of the preceding claims wherein the means (20) for transmitting the force is a striker.

17. A drug delivery device as claimed in claim 16 wherein the striker is a hammer.

18. A drug delivery device as claimed in claim 16 or 17 wherein a region (38) of the striker is shaped to fit a correspondingly shaped surface (42b) in a wall (42) separating the upper (28) and lower (30) barrels defined by the housing (12) such that the striker (20) is aligned to strike the drive pin (108) or other element in the packaged drug (100) on actuation.

19. A drug delivery device as claimed in claim 18 wherein the striker comprises a substantially frustoconical shoulder region (38) which engages a substantially frustoconical surface (42b) in the wall (42) separating the upper (28) and lower (30) barrels defined by the housing (12).

20. A drug delivery device as claimed in claim 15 wherein the means (20) for transmitting the force comprises a substantially conical end (20a) and the spring follower (36) has a correspondingly shaped recess (36a) in the underside thereof.

21. A drug delivery device as claimed in any of the preceding claims wherein the packaged drug (100) and striker (20) are slidably mounted in the device such that the device can be can be primed by pushing the device against the skin.

22. A drug delivery device as claimed in any of claims 19 – 21 wherein the device comprises a slewing spring (44), a sliding piston (48) having an aperture (46) therein and the striker (20), all housed in the lower barrel (30) and the device is triggered by the sliding of the piston (48) up the lower barrel (30) until shoulder region (38) of the striker (20) engages shaped surface (42b) and aligns the striker with the aperture (46) in the sliding piston (48) such that the striker moves down the aperture under the action of the force generating means (14).

23. A drug delivery device as claimed in any of the preceding claims wherein the device is primed and actuated by a single action.

24. A device as claimed in claim 23 wherein pushing the packaged drug (100) up the lower barrel (30) with sufficient force causes the device to be primed and actuated.

25. A device as claimed in claim 23 or 24 wherein the action of pushing the packaged drug up the lower barrel (30) with sufficient force causes the sliding piston (48) to move up the lower barrel (30) thereby causing the striker (20) to be pushed up the lower barrel (30) out of a first position in which it is not axially aligned with the aperture (46) in the sliding piston which operatively communicates with the packaged drug and at the same time acts on a spring follower (36) in the upper barrel (28) causing the spring (14) to be compressed and the device primed such that when the required delivery force is generated the striker (20) is axially aligned with the aperture (46) of the sliding piston (48) and is thus actuated such that the spring (14) acts through the spring follower (36) and striker (20) upon the drive pin (108) or a like element in the packaged drug (100) to deliver the drug (16) into the human or animal body.

26. A device as claimed in any of claims 1 – 22 wherein the device is primed and actuated by two separate actions.

27. A drug delivery device as claimed in any of claims 2 - 25 wherein the upper barrel and lower barrel are formed as separate components.

28. A drug delivery device as claimed in any of the preceding claims wherein the drug is in a contained form.

29. A drug delivery device as claimed in claim 28 wherein the drug is either:
a liquid contained by a membrane;
a liquid with a viscosity of at least 500 centipoises, more preferably at least 5000 centipoises, and more preferably still at least 100,000 centipoises;
a semi solid,
a paste,
a gel or a solid.

30. A drug delivery device as claimed in claim 1 further comprising a packaged drug as an integral part of the device.

31. A drug delivery device as claimed in any of the preceding claims in which the device and/or packaged drug is sealed in a foil pouch or the like to prevent ingress of, for example, moisture, oxygen, light, bacteria or other drug degrading or contaminating agents.

32. A drug delivery device as claimed in any of the preceding claims wherein the tip of the pioneer projectile or needle is positioned a few mm in from end (104) of the packaging (18) such that it is moving when contacting the skin.

33. A drug delivery device as claimed in any of the preceding claims wherein the end (104) about the exit of the channel (106) is in the form of a substantially annular ring located immediately about the channel (106) exit and having a depth and width in the range 1.5mm to 6 mm.

34. A drug delivery device as claimed in any of the preceding claims further comprising a positive lock retention system to ensure the packaged drug (100) does not come away from the device under gravity yet is free to slide up the device.

35. A single use drug delivery device (10) comprising:
i) a housing (12);

ii) a pre-primed means (14) for generating a force capable of pushing a drug (16) from a packaging (18) into a human or animal body;

iii) a means (20) for transmitting said force to push the drug (16) from the packaging (18) into the human or animal body;

iv) a packaged drug (100) forming an integral part of the device; and

v) a means for triggering the device

wherein said force generating means (14) and said force transmitting means (20) are configured to push the drug (16) from the packaging (18) into the human or animal body at a velocity of less than 20m/s.

36. A device as claimed in claim 35 wherein the means for triggering the device is an actuation button or like element.

37. A single use drug delivery device (10) comprising:

i) a housing (12);

ii) a means (14) for generating a force capable of pushing a drug (16) from a packaging (18) into a human or animal body;

iii) a means (20) for transmitting said force to push the drug (16) from the packaging (18) into the human or animal body;

iv) a packaged drug (100) forming an integral part of the device;

v) a means for priming (24) the device; and

vi) a means (38, 42b) for triggering the device

wherein said force generating means (14) and said force transmitting means (20) are configured to push the drug (16) from the packaging (18) into the human or animal body at a velocity of less than 20m/s.

38. A packaged drug (100), for use with a drug delivery device, comprising a packaging (18) containing a drug (16), said packaging (18) comprising a housing (18a, 18b) having a channel (106) running there through and in which is disposed a drive pin or other element (108), a skin piercing means (110; 112), and the drug (16), said housing (18a, 18b) further comprising

i) a region (102) allowing the packaged drug (100) to be slidably mounted to the drug delivery device (10); and

ii) an end (104) adapted to engage and tension the skin.

39. A packaged drug as claimed in claim 38 wherein the skin piercing means is a pioneer projectile (110), syringe needle (112) or the head of a drug splinter.

40. A packaged drug as claimed in claim 38 or 39 wherein the drug is in the form of a drug splinter.

41. A packaged drug as claimed in any of claims 38 to 40 wherein the housing is adapted to ensure the packaged drug positively locks to the device yet is free to slide therein.

42. A packaged drug (100) as claimed in any of claims 38 – 41 wherein the packaging (18) is substantially T- shaped.

43. A packaged drug as claimed in any of claims 38 – 42 wherein the drive pin has a flat and/or an enlarged head (108a).

44. A packaged drug as claimed in any of claims 38 – 43 further comprising a resilient means (114) below the drive pin head to ensure the drive pin is withdrawn after use.

45. A packaged drug as claimed in any of claims 38– 42 in which the packaging comprises a two-part housing (18a, 18b).

46. A packaged drug as claimed in any of claims 38 to 42 comprising a pioneer projectile.

47. A packaged drug as claimed in any of claims 38 to 46 wherein the drug is held in a contained state.

48. A packaged drug as claimed in any of claims 38 to 47 wherein a hollow injection needle (112) is disposed in the channel (106) towards end (104) and a contained liquid drug (16) is disposed in the channel (106) there above.

49. A packaged drug as claimed in claim 48 wherein the contained liquid drug comprises a receptacle (120) slidably disposed in the channel and having a puncturable base (122), a top (124) sealable with the drive pin or element (108) for pushing

i) the receptacle against the needle, and

ii) the needle into the human or animal body

thereby causing the release of the drug (16) out of the channel and into the human or animal body when it is acted upon by the device (10)

50. A packaged drug as claimed in claim 48 further comprising a resilient spacer (126) between the needle and the receptacle.

51. A packaged drug as claimed in any of claims 48 to 50 further comprising a resilient means (114) associated with the needle such that the needle is automatically withdrawn after use.

52. A packaged drug as claimed in any of claims 48 to 51 in which the needle is sharp at both of its ends.

53. A packaged drug as claimed in claim 38 comprising a receptacle (120) housing the drug (16) said receptacle having a breakable base (122) and being sealed by the drive pin (108) or other element which drive pin or other element comprises an elongate body (127) and a plurality of flexible arms (128).

54. A packaged drug as claimed in claim 53 in which the arms (128) of said element (108), in use, ride over one or more ramped surfaces (130) provided on the housing such that they are displaced and / or break away from the elongate body (127) so the elongate body of the drive pin can travel down the receptacle (120), causing the drug (16) to be expelled from the base(122) of the receptacle which breaks under the pressure exerted thereon.

55. A packaged drug as claimed in claim 53 or 54 further comprising a pioneer projectile (110) below the base of the receptacle.

56. A packaged drug as claimed in claim any of claims 38-55 wherein a placebo is disposed behind the drug (16).

57. A method of delivering a drug to a human or animal body through the skin comprising administering a drug using a device as claimed in any of claims 1 to 37 or a packaged drug as claimed in any of claims 38 to 56.

CLAIMS

1. A drug delivery device (10) comprising:

i) a housing (12);

ii) a means (14) for generating a force capable of pushing a drug (16) from a packaging (18) into a human or animal body;

iii) a means (20) for transmitting said force to push the drug (16) from the packaging (18) into the human or animal body; and

iv) a means (38, 42b) for triggering the device

wherein said force generating means (14) and said force transmitting means (20) are configured to push the drug (16) from the packaging (18) into the human or animal body at a velocity of less than 20m/s.

2. A drug delivery device as claimed in claim 1 wherein the housing defines:

i) an upper barrel (28), at one end of the device, which houses the force generating means (14); and

ii) a lower barrel (30), at the end remote from the upper barrel, which houses:

a) a packaged drug (100); and

b) the means (20) for transmitting said force to push the drug (16) from the packaging (18)

said lower barrel being in operative communication with said upper barrel and said packaged drug (100).

3. A drug delivery device (10) as claimed in claim 2 further comprising

v) a means (22) for receiving the packaged drug (100); and

vi) a means (24) for priming the device.

4. A drug delivery device as claimed in any of the preceding claims wherein the means (14) for generating a force capable of pushing a drug (16) from a packaging (18) into a human or animal body delivers a force of from 10 - 40N.

5. A drug delivery device as claimed in any claim 2 wherein the means (20) for transmitting said force to push the drug (16) from the packaging (18) causes the drug to be pushed from the packaging at less than 10m/s.

6. A drug delivery device as claimed in claim 3 wherein said packaged drug (100) is slidably disposed in the means (22) for receiving the packaged drug.

7. A drug delivery device as claimed in any of claims 2 to 6 wherein the packaged drug (100) is slidably disposed in the lower barrel (30) and comprises a packaging (18) containing a drug (16), said packaging comprising a housing (18a, 18b) having a channel (106; 106a, 106b) running there through in which is disposed a drive pin or other element (108), a skin piercing means (110; 112) and the drug (16);
said housing further comprising

i) a region (102) allowing the packaged drug to be slidably mounted to the drug delivery device (10) at receiving means (22); and

ii) an end (104) adapted to engage and tension the skin.

8. A drug delivery device as claimed in claim 7 wherein the skin piercing means is a pioneer projectile (110), a syringe needle (112) or the head of a drug splinter.

9. A drug delivery device as claimed in claim 7 or 8 wherein the drive pin or other element (108) has a flat or enlarged head (108a).

10. A drug delivery device as claimed in claim 7, 8 or 9 further comprising a resilient means (114) below or otherwise in association with the drive pin or other element (108) to ensure the drive pin is withdrawn after use.

11. A drug delivery device as claimed in any of the preceding claims wherein the means (14) for generating the force capable of pushing the drug (16) is a spring.

12. A drug delivery device as claimed in claim 11 wherein the spring is a coil or gas spring.

13. A drug delivery device as claimed in claims 11 or 12 wherein the force generated by the spring is adjustable.

14. A drug delivery device as claimed in claim 13 wherein a screw cap (32) and compression bar (34) provide a means for adjusting the force generated by the spring.

15. A drug delivery device as claimed in any of claims 11 - 14 further comprising a spring follower (36).

16. A drug delivery device as claimed in any of the preceding claims wherein the means (20) for transmitting the force is a striker.

17. A drug delivery device as claimed in claim 16 wherein the striker is a hammer.

18. A drug delivery device as claimed in claim 16 or 17 wherein a region (38) of the striker is shaped to fit a correspondingly shaped surface (42b) in a wall (42) separating the upper (28) and lower (30) barrels defined by the housing (12) such that the striker (20) is aligned to strike the drive pin (108) or other element in the packaged drug (100) on actuation.

19. A drug delivery device as claimed in claim 18 wherein the striker comprises a substantially frustoconical shoulder region (38) which engages a substantially frustoconical surface (42b) in the wall (42) separating the upper (28) and lower (30) barrels defined by the housing (12).

20. A drug delivery device as claimed in claim 15 wherein the means (20) for transmitting the force comprises a substantially conical end (20a) and the spring follower (36) has a correspondingly shaped recess (36a) in the underside thereof.

21. A drug delivery device as claimed in any of the preceding claims wherein the packaged drug (100) and striker (20) are slidably mounted in the device such that the device can be can be primed by pushing the device against the skin.

22. A drug delivery device as claimed in any of claims 19 – 21 wherein the device comprises a slewing spring (44), a sliding piston (48) having an aperture (46) therein and the striker (20), all housed in the lower barrel (30) and the device is triggered by the sliding of the piston (48) up the lower barrel (30) until shoulder region (38) of the striker (20) engages shaped surface (42b) and aligns the striker with the aperture (46) in the sliding piston (48) such that the striker moves down the aperture under the action of the force generating means (14).

23. A drug delivery device as claimed in any of the preceding claims wherein the device is primed and actuated by a single action.

24. A device as claimed in claim 23 wherein pushing the packaged drug (100) up the lower barrel (30) with sufficient force causes the device to be primed and actuated.

25. A device as claimed in claim 23 or 24 wherein the action of pushing the packaged drug up the lower barrel (30) with sufficient force causes the sliding piston (48) to move up the lower barrel (30) thereby causing the striker (20) to be pushed up the lower barrel (30) out of a first position in which it is not axially aligned with the aperture (46) in the sliding piston which operatively communicates with the packaged drug and at the same time acts on a spring follower (36) in the upper barrel (28) causing the spring (14) to be compressed and the device primed such that when the required delivery force is generated the striker (20) is axially aligned with the aperture (46) of the sliding piston (48) and is thus actuated such that the spring (14) acts through the spring follower (36) and striker (20) upon the drive pin (108) or a like element in the packaged drug (100) to deliver the drug (16) into the human or animal body.

26. A device as claimed in any of claims 1 – 22 wherein the device is primed and actuated by two separate actions.

27. A drug delivery device as claimed in any of claims 2 - 25 wherein the upper barrel and lower barrel are formed as separate components.

28. A drug delivery device as claimed in any of the preceding claims wherein the drug is in a contained form.

29. A drug delivery device as claimed in claim 28 wherein the drug is either:
a liquid contained by a membrane;
a liquid with a viscosity of at least 500 centipoises, more preferably at least 5000 centipoises, and more preferably still at least 100,000 centipoises;
a semi solid,
a paste,
a gel or a solid.

30. A drug delivery device as claimed in claim 1 further comprising a packaged drug as an integral part of the device.

31. A drug delivery device as claimed in any of the preceding claims in which the device and/or packaged drug is sealed in a foil pouch or the like to prevent ingress of, for example, moisture, oxygen, light, bacteria or other drug degrading or contaminating agents.

32. A drug delivery device as claimed in any of the preceding claims wherein the tip of the pioneer projectile or needle is positioned a few mm in from end (104) of the packaging (18) such that it is moving when contacting the skin.

33. A drug delivery device as claimed in any of the preceding claims wherein the end (104) about the exit of the channel (106) is in the form of a substantially annular ring located immediately about the channel (106) exit and having a depth and width in the range 1.5mm to 6 mm.

34. A drug delivery device as claimed in any of the preceding claims further comprising a positive lock retention system to ensure the packaged drug (100) does not come away from the device under gravity yet is free to slide up the device.

35. A single use drug delivery device (10) comprising:
i) a housing (12);

ii) a pre-primed means (14) for generating a force capable of pushing a drug (16) from a packaging (18) into a human or animal body;
iii) a means (20) for transmitting said force to push the drug (16) from the packaging (18) into the human or animal body;
iv) a packaged drug (100) forming an integral part of the device; and
v) a means for triggering the device
wherein said force generating means (14) and said force transmitting means (20) are configured to push the drug (16) from the packaging (18) into the human or animal body at a velocity of less than 20m/s.

36. A device as claimed in claim 35 wherein the means for triggering the device is an actuation button or like element.

37. A single use drug delivery device (10) comprising:
i) a housing (12);
ii) a means (14) for generating a force capable of pushing a drug (16) from a packaging (18) into a human or animal body;
iii) a means (20) for transmitting said force to push the drug (16) from the packaging (18) into the human or animal body;
iv) a packaged drug (100) forming an integral part of the device;
v) a means for priming (24) the device; and
vi) a means (38, 42b) for triggering the device
wherein said force generating means (14) and said force transmitting means (20) are configured to push the drug (16) from the packaging (18) into the human or animal body at a velocity of less than 20m/s.

38. A packaged drug (100), for use with a drug delivery device, comprising a packaging (18) containing a drug (16), said packaging (18) comprising a housing (18a, 18b) having a channel (106) running there through and in which is disposed a drive pin or other element (108), a skin piercing means (110; 112), and the drug (16), said housing (18a, 18b) further comprising

i) a region (102) allowing the packaged drug (100) to be slidably mounted to the drug delivery device (10); and

ii) an end (104) adapted to engage and tension the skin.

39. A packaged drug as claimed in claim 38 wherein the skin piercing means is a pioneer projectile (110), syringe needle (112) or the head of a drug splinter.

40. A packaged drug as claimed in claim 38 or 39 wherein the drug is in the form of a drug splinter.

41. A packaged drug as claimed in any of claims 38 to 40 wherein the housing is adapted to ensure the packaged drug positively locks to the device yet is free to slide therein.

42. A packaged drug (100) as claimed in any of claims 38 – 41 wherein the packaging (18) is substantially T- shaped.

43. A packaged drug as claimed in any of claims 38 – 42 wherein the drive pin has a flat and/or an enlarged head (108a).

44. A packaged drug as claimed in any of claims 38 – 43 further comprising a resilient means (114) below the drive pin head to ensure the drive pin is withdrawn after use.

45. A packaged drug as claimed in any of claims 38– 42 in which the packaging comprises a two-part housing (18a, 18b).

46. A packaged drug as claimed in any of claims 38 to 42 comprising a pioneer projectile.

47. A packaged drug as claimed in any of claims 38 to 46 wherein the drug is held in a contained state.

48. A packaged drug as claimed in any of claims 38 to 47 wherein a hollow injection needle (112) is disposed in the channel (106) towards end (104) and a contained liquid drug (16) is disposed in the channel (106) there above.

49. A packaged drug as claimed in claim 48 wherein the contained liquid drug comprises a receptacle (120) slidably disposed in the channel and having a puncturable base (122), a top (124) sealable with the drive pin or element (108) for pushing

i) the receptacle against the needle, and

ii) the needle into the human or animal body

thereby causing the release of the drug (16) out of the channel and into the human or animal body when it is acted upon by the device (10)

50. A packaged drug as claimed in claim 48 further comprising a resilient spacer (126) between the needle and the receptacle.

51. A packaged drug as claimed in any of claims 48 to 50 further comprising a resilient means (114) associated with the needle such that the needle is automatically withdrawn after use.

52. A packaged drug as claimed in any of claims 48 to 51 in which the needle is sharp at both of its ends.

53. A packaged drug as claimed in claim 38 comprising a receptacle (120) housing the drug (16) said receptacle having a breakable base (122) and being sealed by the drive pin (108) or other element which drive pin or other element comprises an elongate body (127) and a plurality of flexible arms (128).

54. A packaged drug as claimed in claim 53 in which the arms (128) of said element (108), in use, ride over one or more ramped surfaces (130) provided on the housing such that they are displaced and / or break away from the elongate body (127) so the elongate body of the drive pin can travel down the receptacle (120), causing the drug (16) to be expelled from the base(122) of the receptacle which breaks under the pressure exerted thereon.

55. A packaged drug as claimed in claim 53 or 54 further comprising a pioneer projectile (110) below the base of the receptacle.

56. A packaged drug as claimed in claim any of claims 38-55 wherein a placebo is disposed behind the drug (16).

57. A method of delivering a drug to a human or animal body through the skin comprising administering a drug using a device as claimed in any of claims 1 to 37 or a packaged drug as claimed in any of claims 38 to 56.

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Article Abstract

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Transdermal Drug Delivery by Jet Injectors: Energetics of Jet Formation and Penetration

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Abstract
Purpose. Pressure-driven jets have been used for intradermal delivery of a variety of drugs. Despite their introduction into clinical medicine, variability and occasional bruising have limited their widespread acceptance. Although numerous clinical studies of jet injectors have been reported in the literature, surprisingly little is known about the mechanisms of jet penetration into the skin. In this article, we report results of our studies aimed at determining the dependence of drug delivery on jet velocity and diameter. These studies were performed using two experimental models, porcine skin and human skin. Our rationale for using two models was to explore the possibility of using porcine skin as a model for human skin.
Methods. Dermal penetration of jets possessing a range of diameters from 76 μm to 559 μm and a range of velocities from 80 m/s to 190 m/s was studied into human and porcine skin. Penetration was quantified using radiolabeled mannitol. Pressure and velocity of the jets were measured using a calibrated pressure transducer and high-speed photography.
Results. Penetration of the jet into the skin was determined by two main parameters, jet diameter and average jet velocity. Substantial variation in jet penetration into porcine skin was observed for skin pieces obtained from different anatomic locations. For porcine skin, a parabolic dependence of jet delivery on velocity and diameter was observed. The threshold velocity is suggested to be between 80 and 100 m/s for a jet diameter of 152 μm. Above the threshold velocity, the delivery increased for velocities up to 150 m/s, after which delivery decreased with increasing velocity. At a constant velocity of 150 m/s, jet delivery exhibited a maximum at a diameter of 152 μm. Results obtained with human skin were qualitatively similar but quantitatively different. The threshold velocity for jet penetration into human skin was comparable with that in porcine skin; however, the maxima observed in jet delivery into porcine skin with respect to jet velocity was not apparent for human skin over the range of velocities explored.
Conclusions. These studies offer a quantitative analysis of jet penetration into the skin.

Keywords
jet injector, transdermal, skin, penetration, velocity, needle-free

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